

REMARKS

Claim Summary

Claims 17 and 28 are currently amended. Claim 18 was previously canceled. Claims 1-16 and 21-27 are withdrawn from consideration. Claims 29 and 30 are new. Claims 1-17 and 19-30 are currently pending.

Interview

Applicants thank the Examiner for conducting the telephone interview on June 24, 2009, during which independent claim 17 and Solem, U.S. Pub. No. 2003/0135267, were discussed.

Amendment to the Specification

Applicants are adding a paragraph and figure from U.S. Application No. 10/429,172 (U.S. Pub. No. 2004/0220654), which was incorporated by reference in the instant application as filed (see paragraphs [0004] and [0032]). The added paragraph is the same as paragraph [0049] in U.S. Application No. 10/429,172. The reference numbers in the added paragraph have been amended so as not to conflict with reference numbers in the instant application. Applicants are also adding Figure 15, which is Figure 8 from the 10/429,172 application. No new matter is added.

Drawings

New drawing sheet 9 (Fig. 15) has been added by this amendment, the support for which can be found throughout the specification.

Information Disclosure Statements

Applicants note with thanks that the Examiner has considered all references submitted in an Information Disclosure Statement dated 3/10/2009.

Although the Information Disclosure Statements dated 10/2/2008 and 12/22/2008 were indicated as acknowledged by the Examiner (and page 1 of both IDSs is acknowledged), indication of acknowledgment is absent from page 2 on the returned PTO 1449 Forms. Applicants respectfully request updated/corrected versions of the PTO 1449 forms indicating acknowledgment of pages 2 of the IDSs.

Additional references submitted in an Information Disclosure Statement dated 1/17/2008 remain unacknowledged. It is respectfully requested that this Information Disclosure Statement be considered and the PTO Form 1449 be initialed and returned with the next Action.

Claim Rejections Under 35 U.S.C. § 112

Claims 17, 19, 20 and 28 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Without agreeing or acquiescing to the rejections, independent claim 17 is currently amended. Claim 28 has been rewritten in independent form. Applicants respectfully request the rejections be withdrawn.

Claim Rejections Under 35 U.S.C. § 102

Claims 17, 19, 20 and 28 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Solem et al., U.S. 2003/0135267.

Solem describes, in reference to the embodiment in Figures 21, 22 and 23-25, releasing expandable stents 22 and 23 so that they can expand and provide for a temporary fixation of the device in the coronary sinus (*see* [1046], lines 12-16). The stents 22 and 23 then grow into the wall of the coronary sinus ([0147], lines 1-3), while the resorbable sheath or threads are resorbed by the body ([0147], lines 3-5). Once the resorbable sheath has been resorbed to such a degree that it can no longer hold the shape memory metal thread 20 in the straightened shape, the shape memory metal thread retracts and the device is transformed to its activated shorter shape as shown in Figure 25. This shortening of the device makes it bend towards the mitral valve annulus, moving the posterior part forward. This movement reduces the circumference of the annulus and closes the gap between the valve leaflets (*see* [0147], lines 14-22). Solem describes reducing the circumference of the annulus *after* both stents have been anchored in the coronary sinus. In fact, both stents in Solem must be fixed in the coronary sinus before the shape memory metal thread changes configuration in order for the device to function as intended.

Solem does not anticipate claim 17 because it does not describe each and every limitation in claim 17. For example, claim 17 recites, in part, “applying a proximally directed force on the distal anchor, wherein applying the proximally directed force on the distal anchor applies a shaping force from the focal deflector against the lumen wall to modify the shape of the target tissue; and expanding the proximal anchor to anchor the proximal anchor in the lumen, wherein

anchoring the proximal anchor occurs before ceasing the proximally directed force.” These claim limitations find support in the specification in, for example, paragraph [0028], lines 10-14 (“anchoring a proximal anchor ... *to maintain* the device’s ... reshaping of the tissue”); paragraph [0034]; and in the paragraph added by this amendment, which is a paragraph from an application incorporated by reference. The Examiner will note that the “anchor and cinch” method of deployment as described includes modifying the shape of the target tissue *before* the proximal anchor is anchored in place.

In the Office Action mailed 3/19/2009, the Examiner asserts that Solem describes the memory metal thread 20 applying a proximally directed force on the distal stent as soon as the distal stent and a portion of the memory metal thread are out of the introduction sheath, which occurs before the proximal stent is expanded. (*see* page 3, lines 1-6). Even if, *arguendo*, the metal thread inherently applies some type of proximally directed force on the distal stent as soon as the metal thread is released, this does *not* result in a shaping force being applied against the lumen wall to modify the shape of the target tissue, as is required by claim 17. Solem only describes modifying the shape of the annulus *after* both anchors are fixed in place. Solem therefore does not describe each and every limitation in claim 17 and does not anticipate claim 17. Claims 19 and 20 depend from claim 17 and are not anticipated by Solem for at least the reasons set forth above.

Independent claim 28 is currently amended and includes limitations from claim 17. Claim 28 recites, in part, “applying a proximally directed force on the distal anchor, wherein applying the proximally directed force on the distal anchor applies a shaping force from the focal deflector against the lumen wall to modify the shape of the target tissue; and expanding the proximal anchor to anchor the proximal anchor, wherein expanding the proximal anchor occurs while applying the proximally directed force.” These claim limitations find support in the specification, for example, in paragraph [0009], lines 7-8; paragraph [0028], lines 10-14 (“anchoring a proximal anchor ... *to maintain* the device’s ... reshaping of the tissue”); paragraph [0034]; and in the paragraph added by this amendment. The Examiner will note that the “anchor and cinch” method of deployment as described in the specification includes modifying the shape of the target tissue *before* the proximal anchor is anchored in place.

Solem describes modifying the annulus only *after* the proximal stent is anchored in place. Solem simply does not describe performing any step which *modifies target tissue* while

expanding the proximal anchor. Solem therefore does not describe applying a proximally directed force on a distal anchor which applies a shaping force from a focal deflector against the lumen wall to modify the shape of the target tissue, wherein expanding the proximal anchor occurs while applying the proximally directed force, as is required by claim 28. Claim 28 is therefore not anticipated by Solem.

Double Patenting

Claim 17 stands rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 15 of Alferness et al., U.S. 6,908,478. Claim 17 is patentably distinct from claim 15. For example, claim 17 includes “applying a proximally directed force on the distal anchor, wherein applying the proximally directed force on the distal anchor applies a shaping force from the focal deflector against the lumen wall to modify the shape of the target tissue; and expanding the proximal anchor to anchor the proximal anchor in the lumen, wherein anchoring the proximal anchor occurs before ceasing the proximally directed force.” At least these claim limitations render claim 17 patentable over claim 15.

New Claims

Applicants are adding new claims 29 and 30. Support for the new claims can be found throughout the specification as filed. For example, support can be found in, at least, paragraph [0009], lines 7-8; paragraph [0028], lines 10-14; paragraph [0034]; and in the paragraph added by this amendment.

As is set forth above, Solem does not disclose applying a proximally directed force on the distal anchor, wherein applying the proximally directed force on the distal anchor applies a shaping force from the focal deflector against the lumen wall which modifies the shape of the target tissue, and anchoring the proximal anchor after the shape of the target tissue has been modified, as is required by new independent claim 29. Solem describes anchoring the proximal stent *before* the annulus shape is changed.

CONCLUSION

Applicants request reconsideration and allowance of all claims pending in this application. If a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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